OCT 15 2010

Section 5 – 510(k) Summary

Submitter:	St. Jude Medical - Atrial Fibrillation Division 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 3005188751
Contact Person:	Wendy Pinor Sr. Regulatory Affairs Specialist Phone (651) 756-5223 Fax (952) 930-9481
Date Prepared:	July 9, 2010
Trade Name:	St. Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter
Classification:	Class II - 21 CFR 870.1220 Electrode recording catheter or electrode recording probe
Product Code:	DRF
Predicate Device(s):	The subject device is equivalent to the following St. Jude Medical devices: • St. Jude Medical Livewire Electrophysiology Catheter • MediGuide Guided Measurement Catheter (GMC)
Device Description:	The MediGuide Enabled Livewire Steerable Electrophysiology Catheter is designed to allow electrophysiological mapping at various endocardial and intravascular sites, including the inferior vena cava, superior vena cava, pulmonary veins and coronary sinus. The use of the MediGuide Enabled Livewire diagnostic mapping catheter in conjunction with the MediGuide gMPS system allows real-time tip positioning and navigation during routine diagnostic evaluation. When connected to the ECG, the MediGuide Enabled Livewire Catheter will transmit routine electrical signals while the passive sensor at the tip of the catheter is tracked by gMPS and is superimposed on any 2D X-ray image in real time ("Live") fluoroscopy mode (the actual 3D position of the catheter tip is projected on the real time 2D image).
Intended Use:	The SJM MediGuide Enabled Catheter™ can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites. The MediGuide Enabled Catheter™ is used with a compatible gMPS™ system to enable real-time tip positioning and navigation.

	The MediGuide System is indicated for use as an adjunct to fluoroscopy
Comparison to Predicate Devices	The MediGuide Enabled Livewire Steerable Electrophysiology Catheter uses similar technology, materials, and design principals as the predicated devices. The dimensional characteristics, indication for use and the fundamental scientific technologies of the predicate devices are also substantially similar.
Conclusion:	St. Jude Medical considers the MediGuide Enabled Livewire Steerable Electrophysiology Catheter to be equivalent to or substantially similar to the predicate devices listed above. This conclusion is based upon the devices' similarities in design, technological characteristics, and principles of operation, materials, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 15 2010

St. Jude Medical
c/o Ms. Wendy Pinor
Sr. Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, MN 55345

Re: K101955
Trade/Device Name: St Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe.
Regulatory Class: Class II (two)
Product Code: DRF
Dated: September 16, 2010
Received: September 17, 2010

Dear Ms. Pinor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 15 2010

510(k) Number (if known): **K101955**

Device Name:

St Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter

Indications for Use:

The SJM MediGuide Enabled Livewire™ steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

The MediGuide Enabled Livewire™ Steerable Electrophysiology Catheter is used with a compatible gMPS™ system to enable real-time tip positioning and navigation.

The MediGuide System is indicated for use as an adjunct to fluoroscopy

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101955